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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,056	12/04/2003	Antonis Zervos	105150-0002	7674

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NUTTER MCCLENNEN & FISH LLP  
WORLD TRADE CENTER WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02210-2604

EXAMINER
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CARTER, KENDRA D

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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01/29/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,056	<b>Applicant(s)</b> ZERVOS, ANTONIS	
	<b>Examiner</b> Kendra D. Carter	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 17-29 and 32-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14 and 17-22 is/are rejected.
- 7) ☒ Claim(s) 24-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 12-31 in the reply filed on September 26, 2007 and March 3, 2007 is acknowledged. There was no grounds given for the traversal, thus the requirement is still deemed proper and is therefore made FINAL.

The Examiner acknowledges the applicant's remarks and arguments of September 26, 2007 made to the office action filed March 27, 2007. Claims 1-14, 17-29 and 32-53 are pending. Claims 12, 13, 17-20 and 24-27 are amended and claims 15, 16, 23, 30 and 31 are canceled. Claims 1-11 and 32-53 are withdrawn.

In light of the amendments and cancellation of the claims, the following rejections and objections are withdrawn: 1) both claim objection of claims 15-19 and 23-27; 2) claim objection to claim 13; 3) 35 U.S.C. 112, first paragraph rejection of claims 12-15 and 17-19; 4) 35 U.S.C. 112, first paragraph rejection of claims 20-22 and 28-29; 5) both 35 U.S.C. 112, first paragraph rejections of claims 30 and 31; 6) provisional obviousness-type double patenting rejection of claims 12-14, 21-22, 28 and 29-31 over

U.S. Patent Application No. 10/369,311; and 7) 35 U.S.C. 102(e) rejection of claims 12-14, 20-22, 28 and 29 as being anticipated by Almemri.

Due to the amendment to the claims, the new objection and rejections are made below.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. The attached copy of PTO Form PTO/SB/08A was not provided as indicated by Applicant.

### ***Claim Objections***

Claims 24-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Also, claims 24-29 would be allowable if amended to reflect the changes suggested by the Examiner in the Conclusion below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description of the compound (I) or a description of what R<sub>2</sub> is in compound (II).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(1) Claims 12-14 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The claim 12 discloses that "...at least one apoptosis inhibiting compound comprising Ucf-101..", which reads on a single compound comprising multiple compounds. A composition can comprise multiple compounds but not the compound itself. For compact prosecution the Examiner has examined the claim to read on a composition comprising multiple apoptosis inhibiting compounds.

(2) Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant has failed to include what  $R_1$  or/and  $R_2$  is for each compound represented in claims 20.

### ***Conclusion***

No claims allowed. The Examiner notes that claims 12-19 would be allowable if claim 12 is re-written in the form of claim 20 and claims 17-19 are re-written in the form of claims 25-27 respectively to overcome the 35 U.S.C. 112 rejection. For instance, claim 12 would read, a method for inhibiting caspase-independent apoptosis in a cell comprising: contacting a cell having Omi/HtrA2 activity with at least one apoptosis inhibiting compound, wherein the apoptosis inhibiting compound is selected from the group consisting of: corrected compounds (I), (II), (III), and (IV), such that the apoptosis

inhibiting compound interacts with Omi/HtrA2 to reduce the activity of Omi/HtrA2, wherein the inhibition of Omi/HtrA2 activity reduces apoptosis in the cell; and monitoring the inhibition of apoptosis. Therefore, claim 17 would read, a method of claim 12, wherein the apoptosis inhibiting compound is Ucf-101 and Ucf-102. Likewise, claims 18 and 19 would be re-written to be similar to the re-written claim 17, but with compounds Ucf-103 and Ucf-104. Claims 20-29 would be allowable if claim 20 is amended to include what  $R_1$  or/and  $R_2$  is for each compound represented in claims 20, and the structure of (I) is corrected. The Examiner further notes that upon making the above amendments, the Applicant should consider cancelling claims 20-29 because a method of reducing Omi/HtrA2 activity is a limitation of claim 12, as well as monitoring the inhibition of apoptosis (claims 28 and 29), which is the result of the reduction of Omi/HtrA2 as disclosed in claim 12.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

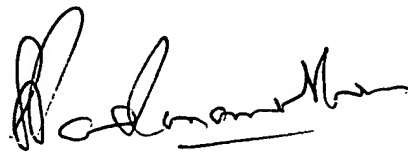
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER